

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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CENTRAL RABBINICAL CONGRESS OF THE USA &
CANADA, AGUDATH ISRAEL OF AMERICA,
INTERNATIONAL BRIS ASSOCIATION, RABBI
SAMUEL BLUM, RABBI AHARON LEIMAN, and
RABBI SHLOIME EICHENSTEIN,

**DECLARATION OF
MICHELLE GOLDBERG-
CAHN**

Plaintiffs,

12 Civ. 7590 (NRB)

-against-

ECF Case

NEW YORK CITY DEPARTMENT OF HEALTH AND
MENTAL HYGIENE, NEW YORK CITY BOARD OF
HEALTH, and DR. THOMAS FARLEY in his official
capacity as Commissioner of the New York City
Department of Health and Mental Hygiene,

Defendants.

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MICHELLE GOLDBERG-CAHN, declares the truth of the following under
penalty of perjury, pursuant to 28 U.S.C. § 1746:

1. I am an Assistant Corporation Counsel in the office of MICHAEL A. CARDOZO, Corporation Counsel of the City of New York, attorney for the defendant City of New York in this action. I submit this declaration in opposition to plaintiffs' motion for a preliminary injunction and to place certain documents on the record of this motion.

2. More specifically, this declaration is submitted to summarize the history of the promulgation of Section 181.21 of the New York City Health Code ("Health Code")¹ – the

¹ The Health Code is part of Title 24 of the Rules of the City of New York ("RCNY").

rule challenged by plaintiffs in this action and provide the Court with copies of the relevant public documents.

3. On June 12, 2012, New York City Department of Health and Mental Hygiene (“DOHMH”) officials presented a proposal to the New York City Board of Health (“Board of Health”) for approval of a proposed rule to amend Article 181 of the Health Code to require a person performing a circumcision involving direct oral suction to inform the parent(s) of the infant of the health risks and to obtain their consent prior to performing the procedure (“Proposed Rule”). A copy of relevant portions of the minutes from the June 12, 2012 Board of Health Meeting is annexed hereto as Exhibit “A.”

4. During the June 12, 2012 Board of Health Meeting, Drs. Varma and Schillinger from DOHMH presented to the Board of Health information about DOHMH’s experience of investigating cases of herpes simplex virus type 1 (“HSV1”) in neonates associated with direct oral suction during circumcision. See Exhibit “A,” at 79-82. Dr. Varma reported that since 2000, DOHMH has eleven (11) laboratory-confirmed cases of neonatal HSV1 “that are associated with direct oral suction being performed during circumcision.” Exhibit “A,” at 80. Dr. Varma stated, in relevant part, as follows:

In these cases, the lesions began in and around the genitalia a median of eight days following circumcision. Of these eleven cases, eight of them resulted in children being hospitalized, two children died, and two suffered brain damage.

We have confirmed that in these eleven cases, that six of them definitely had direct oral suction performed. In the other five it was highly likely to be performed. The reason we couldn’t confirm it is, many times family members were unwilling to describe for us in detail what procedure actually occurred.

Using various methods that we can describe during the comment period, we calculated the risk of herpes infection following direct oral suction to be about one in 4,098. We estimate this risk is

about three or four times greater than the risk of herpes in males who did not have direct oral suction performed in New York City.

There are several lines of evidence that link neonatal herpes to direct oral suction being performed as part of circumcision. First is the location of the lesions. They typically originate in and around the genitalia, which is an uncommon way for neonatal herpes – which is usually transmitted from mother to child – to present initially.

Second is the timing of symptom onset. As we described, these lesions are occurring a median of about eight days after the circumcision is performed, which again, is highly suggestive that it was the acts during circumcision that initiated the risk.

Third, we have at least one cluster of three infections that we have conclusively related to one specific mohel. This was an in-depth that included laboratory as well as epidemiological evidence.

And fourth, we have presented before that we in fact have statistical correlation that shows that there is risk associated with direct oral suction and development of herpes.

And finally, almost all of the cases were HSV type 1, which is commonly found in the mouth. The only two cases that were not HSV were untyped because specimens were not tested appropriately.

Exhibit "A," 80-82.

5. In addition, Dr. Varma presented information regarding the need for consent of the parents. For example, he stated "[i]n at least two of the eleven cases the family members complained to us that they were unaware that direct oral suction would be performed as part of the circumcision ritual." Exhibit "A," at 82. He then discussed other complaints to DOHMH about direct oral suction with circumcision that was not expected. "And we've had phone calls as recently as two weeks ago from noncases [sic]. These are simply parents calling to complain to the agency that direct oral suction was performed during circumcision, and this was not something they would have approved of had they known it was going to be performed."

Id.

6. At the conclusion of the presentation on the consent requirement proposal, the Board of Health approved for publication the Proposed Rule. See Exhibit "A," at 101-102.

7. On June 19, 2012 DOHMH published in the *City Record* a Notice of Public Hearing setting forth the Proposed Rule. As stated in the notice, a public hearing on the proposed rule was scheduled for July 23, 2012 at DOHMH. A copy of the Notice of Public Hearing with the Proposed Rule is annexed hereto as Exhibit "B."

8. The Statement of Basis and Purpose set forth in the Proposed Rule, provided as follows:

The purpose of this amendment is to require written consent from a parent or legal guardian when direct oral suction will be performed during his or her son's circumcision. The written informed consent will be required, which would provide information about the risks involved, including possible infection with herpes simplex virus and its potentially serious consequences, such as brain damage and death. Knowing the risks posed by direct oral suction, a parent or legal guardian can then make an informed choice about whether it should be performed as part of the circumcision.

The proposed amendment will require practitioners of oral suction during circumcision to retain copies of informed consent forms for at least one year and to make them available to the Department upon request.

Background

Male circumcision, which involves cutting off skin and leaving an open wound on the penis, carries a risk for infection, bleeding and penile injury to infants under 60 days of age. Therefore circumcision should be performed under sterile conditions to protect the open wound from infection. A practice known as *metzitzah b'peh*, involves direct contact between the mouth of a person performing circumcision and the infant's circumcised penis ('direct oral suction'). When direct oral suction is performed as part of circumcision, there is a risk that the person performing direct oral suction will transmit herpes simplex virus or other infectious disease to the infant being circumcised.

Between 2004 and 2011, the Department learned of 11 cases of laboratory-confirmed herpes simplex virus infection in male

infants following circumcisions that were likely to have been associated with direct oral suction. Two of these infants died, and at least two others suffered brain damage. The parents of some of these infants have said that they did not know before their child's circumcision that direct oral suction would be performed. In addition, since 2004, the Department has received multiple complaints from parents whose children may not have been infected who were also not aware that direct oral suction was going to be performed as part of their sons' circumcisions.

Exhibit "B."

9. The Proposed Rule would require disclosures of the health risks associated with direct oral suction on an infant by obtaining "written informed consent...which would provide information about the risks involved, including possible infection with herpes simplex virus and its potentially serious consequences, such as brain damage and death." Exhibit "B."

"Direct oral suction" was defined as "contact between the mouth of a person performing a circumcision and the infant's circumcised penis." Exhibit "A," at § 181.21(a).

10. The Notice of Proposed Hearing also invited members of the public to submit written comments to the proposed rule.

11. The Board of Health held a hearing on the proposed rule on July 23, 2012. A transcript of the July 23, 2012 Board of Health public hearing is annexed hereto as Exhibit "C." At the hearing, only three people came to testify about the proposed rule. The three people who testified were all rabbis associated with either the American Board of Ritual Circumcision or the International Bris Association. Their testimony essentially informed the Board of Health that their organizations strictly regulate ritual circumcision, and that their organizations place the infants' health as a paramount concern. Nonetheless, the three rabbis testified that they had grave concerns about DOHMH getting involved with the regulation of ritual circumcision and that they were strongly opposed to the proposed rule. See Exhibit "C."

12. DOHMH received 21 written comments from 18 different sources before and after the July 23, 2012 public hearing. Comments were received from ritual circumcisers, pediatric bioethicists, religious organizations, and private citizens. Copies of the written comments DOHMH received, with numbers handwritten for ease of reference, are collectively annexed hereto as Exhibit "D."

13. DOHMH received eleven comments in favor of the Proposed Rule. See Exhibit "D," Comment Nos. 1, 2, 3, 4, 5 (and 5a), 6, 7, 8, 11, 12, and 18. For instance, on June 18, 2012, DOHMH received a comment from a practicing mohel in the Hasidic community who performs direct oral suction: "If there were a governmental agency which issued guidelines for parents/mohels explaining the risks, it would enable me to have an opportunity to explain and discuss this with parents, thereby letting them decide whether they want to go ahead with it or not. . . . Currently, there is no respectable way for me to refuse to do MbP." Exhibit "D," Comment No. 2.

14. In addition, on June 25, 2012, DOHMH received a comment in favor of the Proposed Rule from a self-described member of the "Brooklyn ultra-Orthodox community," stating, in relevant part: "[F]or my personal situation, a consent form would have served a purpose. Even during the frenzied days following the birth of a child and preparation of the *bris* I would have perused the document and studied the issue. And being someone independent, I would have concluded that common sense and as importantly Jewish law dictates that MbP may not be performed." Exhibit "D," Comment No. 3.

15. Another comment received in favor of the Proposed Rule, came from a certified mohel, dated July 17, 2012, stating the following:

I am writing as a pediatrician, a bioethicist, a Jew and a certified *mohel*[.] This is a situation in which parents and religious leaders

are engaging in a practice that leads to the death of children. Religious freedom may allow adults to make martyrs of themselves. It does not allow parents to make martyrs of their children.

The practice of metzitzah b'pei should be illegal. It is a practice that is quite controversial even among respected rabbinic authorities. It was initially instituted because it was thought to reduce the risk of infection after circumcision. Today, we understand that it increases the risk of infection and even death. The Chief Rabbinate of Israel has stated that it is not essential for a ritual circumcision to be religiously recognized. It endangers children.

Exhibit "D," Comment No. 7.

16. DOHMH also received seven comments in opposition to the Proposed Rule, which collectively explained the religious necessity of direct oral suction, challenged DOHMH's medical findings with respect to the link between direct oral suction and the transmission of HSV, and raised constitutional challenges to the Proposed Rule. Exhibit "D," Comment Nos. 9, 10, 13 (and 13a), 14 (and 14a), 15 (and 15a, 15b, and 15c), 16, and 17.

17. At the conclusion of the July 23, 2012 public hearing, the Board of Health voted to approve the proposed rule and to hold a public hearing on any draft final rule on September 13, 2012. Exhibit "C."

18. Prior to the September 13, 2012 Board of Health meeting, on September 12, 2012, two additional sets of comments were received by Mayor Bloomberg with copies sent to DOHMH. The September 12, 2012 letters are collectively annexed hereto as Exhibit "E." The first letter was from Janet A. Englund, M.D., President of the Pediatric Infectious Diseases Society in support of the proposed rule. The letter, from "the world's largest organization of professionals dedicated to the treatment, control and eradication of infectious diseases affecting children," states that "[t]he risk to the infant from any oral contact to a break in the infant's skin,

particularly at the point and time of circumcision, puts the baby at highest risk for potentially acquiring a life-threatening and frequently lethal herpes infection.” Exhibit “E.”

19. The second letter from Thomas G. Slama, MD, President of the Infectious Diseases Society of America (“ISDA”), which “represents nearly 10,000 physicians and scientist devoted to patient care, research, and public health in infectious disease,” also provided support for the proposed rule. Exhibit “E.” The IDSA letter states, in relevant part, as follows:

... The epidemiological investigations conducted by [DOHMH] present strong evidence that herpes simplex virus type 1 (HSV-1) can be transmitted to a newborn when circumcision involves direct orogenital suction of the penile incision. These investigations further found that newborns receiving orogenital suction after circumcision are at greater risk of contracting HSV infection than circumcised infants who did not. Because neonatal immune systems are underdeveloped, HSV infection in newborns is more likely to result in death or permanent disability. ...

Given the severity of these consequences, the risks associated with MBP as well as the importance of practicing circumcisions and related procedures in a sterile environment should clearly be communicated to parents or legal guardians in advance of the procedure.

Exhibit “E.”

20. On September 13, 2012, the Board of Health held a public meeting wherein the Proposed Rule was discussed. A copy of relevant portions of the transcript of the September 13, 2012 public meeting is annexed hereto as Exhibit “F.”

21. At the September 13, 2012 public meeting, representatives from DOHMH’s Division of Communicable Disease and Bureau of Sexually Transmitted Disease Control & Prevention presented material to the Board of Health regarding the proposed informed consent for direct oral suction rule. A copy of the PowerPoint presentation made by DOHMH Deputy Commissioner Dr. Varma to the members of the Board of Health is annexed hereto as Exhibit “G.”

22. Moreover, a revised proposed final rule was circulated to the members of the Board of Health. A copy is annexed hereto as Exhibit "H." The proposed final rule made minor changes to the Proposed Rule in response to the comments received from the July 23, 2012 public hearing and after publication of the Proposed Rule. Some changes included language to be provided by a person performing a circumcision with direct oral suction if s/he elects to use his/her own forms. Other changes included extending the age of the written informed consent requirement from infants under 60 days to infants under one year of age. Exhibit "H."

23. At the conclusion of the September 13, 2012 Board of Health public meeting, the Board of Health voted unanimously to adopt a resolution approving the revised final amendment to Health Code § 181.21. See Exhibit "F," at 115-16.

24. A copy of the Notice of Adoption of an Amendment to Article 181 of the Health Code is annexed hereto as Exhibit "I."

25. The Notice of Adoption of an Amendment to Article 181 sets forth the Statement of Basis and Purpose of the rule. The Statement of Basis and Purpose provides, as follows:

Statement of Basis and Purpose

The purpose of this amendment is to require written consent from a parent or legal guardian when direct oral suction will be performed during his or her son's circumcision. The written consent will require that the parent or guardian has been told that the Department advises against direct oral suction because of certain risks associated with the practice, including infection with herpes simplex virus and its potentially serious consequences, such as brain damage and death, as well as exposure to other infectious diseases. Knowing the risks posed by direct oral suction, a parent or legal guardian can then make an informed choice about whether it should be performed as part of the circumcision.

The amendment requires persons performing circumcisions which include direct oral suction to retain copies of signed consent forms for at least one year and to make them available to the Department upon request.

Background

Male circumcision, which involves cutting off skin and leaving an open wound on the penis, carries a risk for infection. It should be performed under sterile conditions to protect the open wound from infection. There is a practice involving direct contact between the mouth of a person performing or assisting in performing a circumcision and the infant's circumcised penis ('direct oral suction'). When direct oral suction is performed as part of circumcision, there is a risk that the person performing direct oral suction will transmit herpes simplex virus to the infant being circumcised.

Between 2004 and 2011, the Department learned of 11 cases of laboratory-confirmed herpes simplex virus infections in male infants following circumcisions that were likely to have been associated with direct oral suction. Two of these infants died, and at least two others suffered brain damage. The parents of some of these infants have said that they did not know before their child's circumcision that direct oral suction would be performed. In addition, since 2004, the Department has received multiple complaints from parents whose children may not have been infected with herpes simplex virus or other infectious diseases but who were also not aware that direct oral suction was going to be performed as part of their sons' circumcisions.

The amendment

The new Health Code provision, §181.21 -- Consent for direct oral suction as a part of circumcision -- requires that if direct oral suction is to be performed as part of a circumcision, the person performing the circumcision must obtain prior written consent from a parent or legal guardian. The written consent would document that a parent has been given notice that direct oral suction is to be performed and that the parent has been informed that the Department advises against direct oral suction because the practice carries a risk of transmission to the infant of herpes simplex virus infection or other infectious diseases. A copy of the signed consent form must be given to the parent or legal guardian signing the consent. The person performing the circumcision will have to maintain the original for at least one year after the

circumcision is performed, and make it available for inspection at the request of the Department.

In response to comments received, the resolution has been amended to allow use of a consent form other than one approved and provided by the Department if the form used contains certain elements deemed necessary for a parent or legal guardian to document that she or he has given consent. The language of the consent now includes a reference to the Department's concerns about the risks of direct oral suction, and indicates that the consent must be obtained by the person performing the circumcision whenever direct oral suction is performed regardless of whether this person performs direct oral suction himself or it is done by another person assisting him.

Exhibit "I."

26. The text of the amended rule provides, as follows:

§ 181.21 Consent for direct oral suction as part of a circumcision.

(a) *Direct oral suction* means contact between the mouth of a person performing or assisting in the performance of a circumcision and an infant's circumcised penis.

(b) *Written consent required.* A person may not perform a circumcision that involves direct oral suction on an infant under one year of age, without obtaining, prior to the circumcision, the written signed and dated consent of a parent or legal guardian of the infant being circumcised using a form provided by the Department or a form which shall be labeled "Consent to perform oral suction during circumcision," and which at a minimum shall include the infant's date of birth, the full printed name of the infant's parent(s), the name of the individual performing the circumcision and the following statement: "I understand that direct oral suction will be performed on my child and that the New York City Department of Health and Mental Hygiene advises parents that direct oral suction should not be performed because it exposes an infant to the risk of transmission of herpes simplex virus infection, which may result in brain damage or death."

(c) *Retention of consent forms.* The person performing the circumcision must give the parent or legal guardian a copy of the signed consent form and retain the original for one year from the date of the circumcision, making it available for inspection if requested by the Department.

Exhibit "I."

27. The Notice of Adoption of an Amendment to Article 181 of the Health Code was published in the *City Record* on September 21, 2012. A copy of relevant portions of the September 21, 2012 *City Record* publication is annexed hereto as Exhibit "J."

28. In accordance with New York City Charter § 1043(e), the rule as published was scheduled to become effective on October 21, 2012. As the Court is aware, the parties stipulated to a limited stay of enforcement of the rule until oral argument on plaintiffs' preliminary injunction motion, scheduled for November 14, 2012, at 2:00p.m.

Additional Document for the Consideration by the Court

29. A true and correct copy of relevant portions of the Letters to the Editor in "Hakirah: The Flatbush Journal of Jewish Law and Thought," published in 2006, is annexed hereto as Exhibit "K."

Dated: New York, New York
November 15, 2012



MICHELLE GOLDBERG-CAHN